



Assessing Biosecurity Risks

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Global Security Center

Sandia National Laboratories

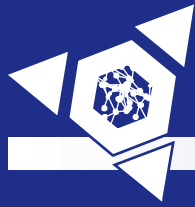
Albuquerque, NM USA

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www.biosecurity.sandia.gov

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Development of a Biosecurity Program

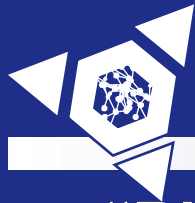
- **Primary Goal of a Biosecurity Program**
 - To prevent loss, theft, or misuse of microorganisms, biological materials, and research-related information.
 - A *vital* factor in the development of an appropriate, applicable Biosecurity Program is **Risk Assessment**
- **Biosecurity Risk Assessment Components**
 - Evaluate the biological agents that exist at a facility
 - Evaluate the facility processes and procedures
 - Evaluate the biorisk mitigation measures that are in place
 - Evaluate the potential adversaries of the facilities



What is Risk?

- Is a function of Likelihood and Consequences

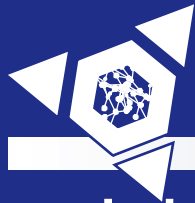




Biorisk

- “Biorisk is the combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological toxin or agent”*
- The source may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.
- **Biorisk is the integration of biosafety and biosecurity**

**CWA 15790 Laboratory Biorisk Management Standard, Feb 2008*



Focus on the Laboratory

- **Laboratory Biosecurity**

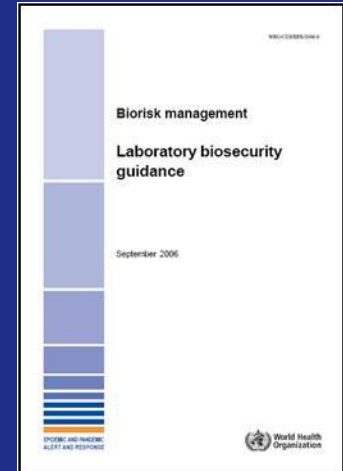
- A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm

- **Laboratory Biosafety**

- Describes the containment principles, technologies, and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release

- **Common strategy**

- Identification of preventive measures is determined by the **RISK ASSESSMENT**
- Biosecurity and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics





Laboratory Biosecurity Risks

Risk = f (Likelihood, Consequence)

- **Likelihood**

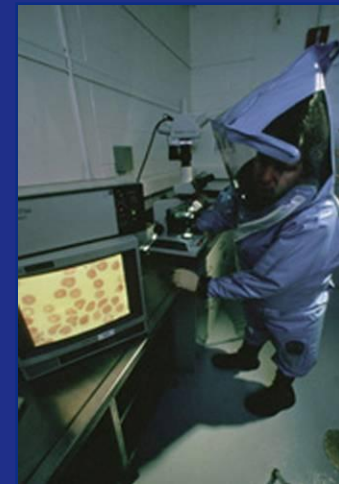
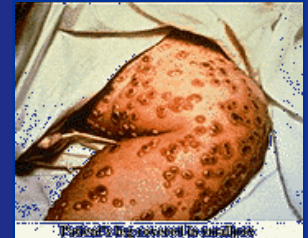
- For security assessments, the likelihood of the adverse event, often referred to as the Threat Potential, includes the Threat, because it is a deliberate event

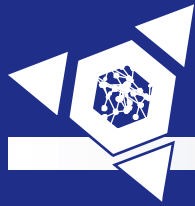
- **Consequences**

- Of infection from accidental exposure or malicious release

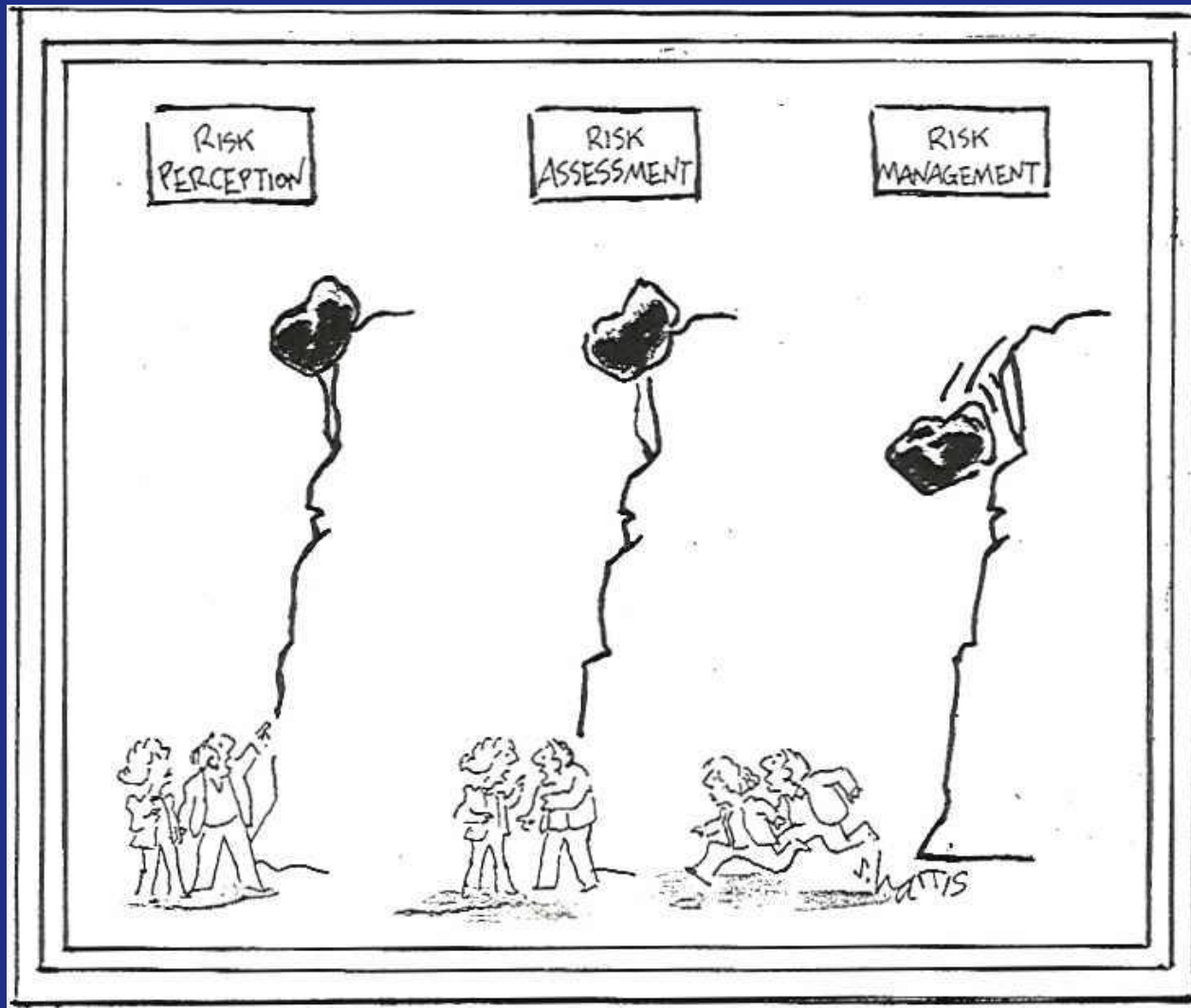
- **Risks**

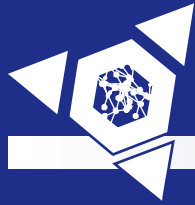
- To laboratory workers
- Risk of accidental or deliberate exposure to community
- Risk of accidental or deliberate exposure to animal community





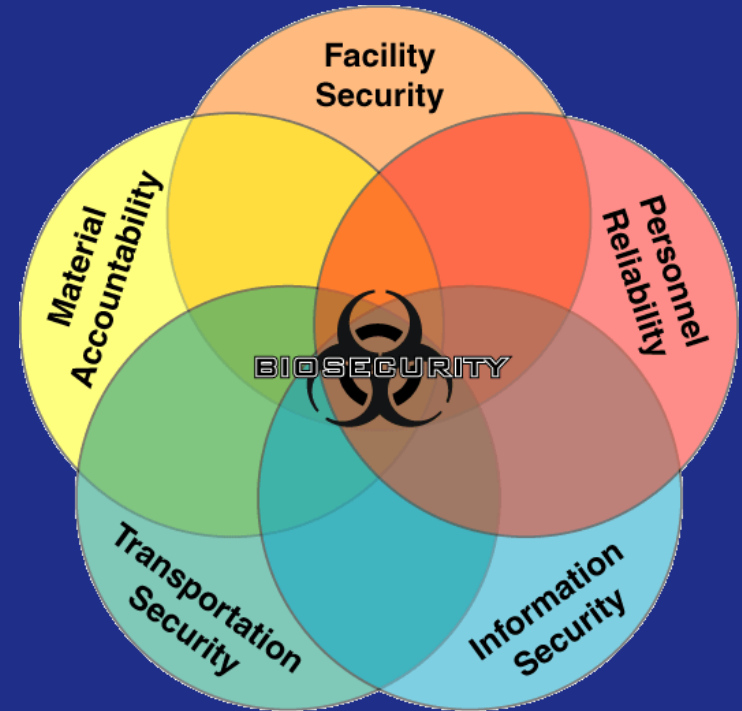
Risk Assessment: Understand the Risks

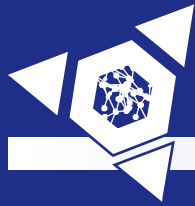




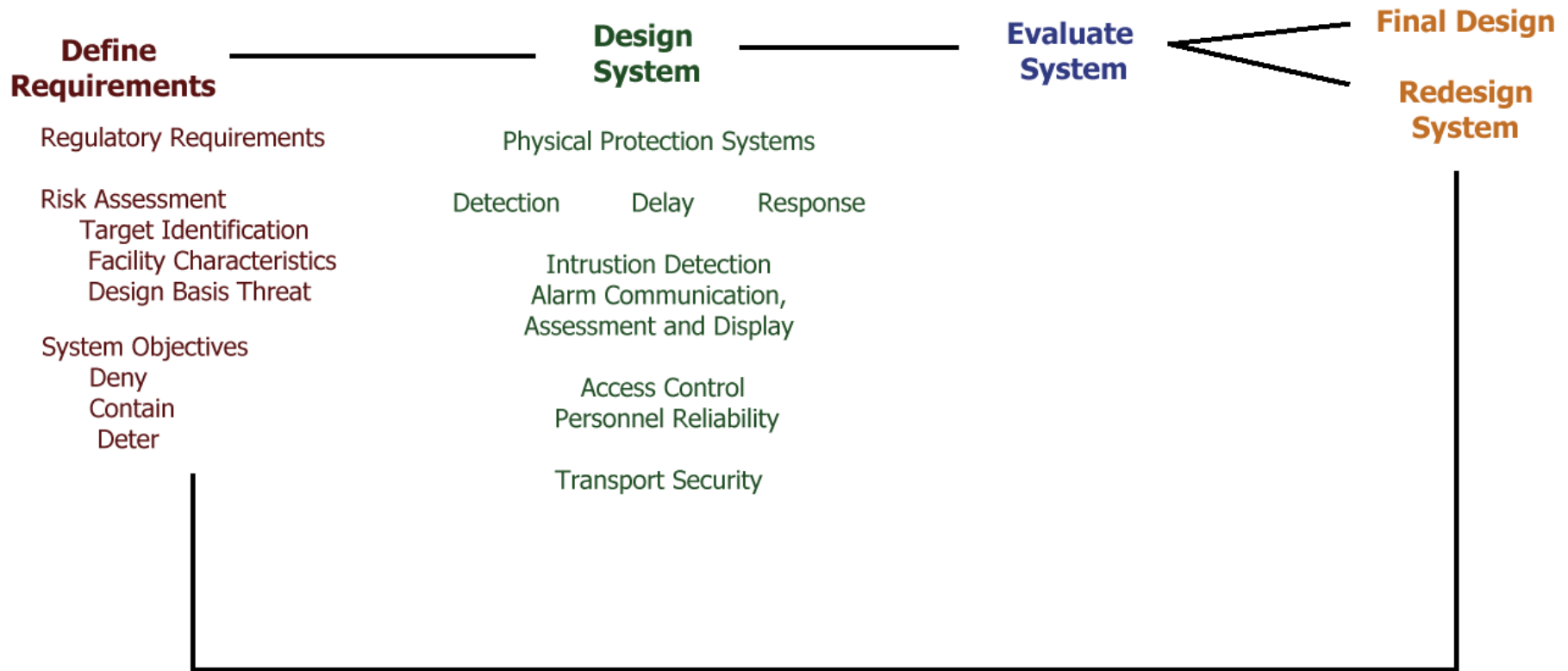
A Systems Approach to Biosecurity Risk Assessment

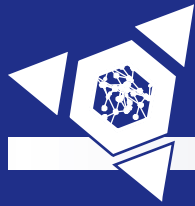
- **Biosecurity system components**
 - Physical security
 - Personnel security
 - Material handling and control measures
 - Transport security
 - Information security
 - Program management practices
- **Each component is implemented based on results of risk assessment**
- **Biosecurity must mitigate risk for both**
 - The insider
 - The outsider





Laboratory Biosecurity Systems



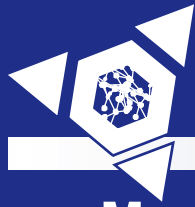


“...given the high level of know-how needed to use disease as a weapon to cause mass casualties, the United States should be less concerned that terrorists will become biologists and far more concerned that biologists will become terrorists.”

-World At Risk,

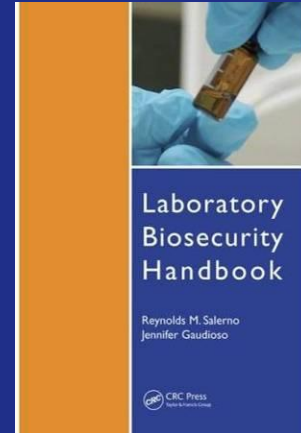
The report of the commission
on the prevention of
weapons of mass destruction
proliferation and terrorism,
December 2008





Biosecurity Risk Assessment Objectives

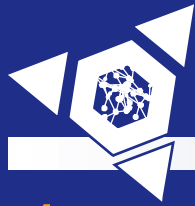
- **Management is responsible for meeting all international, national, and local regulatory requirements**
 - Biological Weapons Convention
 - UN Security Council Resolution 1540
 - National regulations
- **Risk assessment allows management to decide against which scenarios to actively protect – establish a design basis threat**
- **Management determines security system strategy:**
 - **Deny:** prevent adversary from gaining access to particular pathogen or toxin
 - **Contain:** prevent adversary from leaving facility while in possession of stolen pathogen or toxin
 - **Deter:** discourage adversary from stealing a particular pathogen or toxin by making theft of that agent appear very difficult





Risk Assessment Principles

- Ideally the risk assessment is conducted with a standardized, systematic methodology
 - Results repeatable, comparable
- Define the problem (What is the question you are trying to answer)
- The risk assessment method used should be as simple as possible
 - Elaborate when needed
- Those conducting risk assessments should be explicit about uncertainties
- Risk assessment methods can incorporate one or more approaches



Biosecurity Risk Assessment

1. Characterize assets and threats

- Identify and evaluate assets (including pathogens and toxins)
- Evaluate adversaries who might target those assets



2. Evaluate scenarios

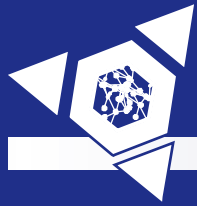
- Create scenarios consisting of “specific adversaries” attempting to target specific assets
- Determine how the various scenarios could be perpetrated (vulnerability assessment)



3. Characterize the risk

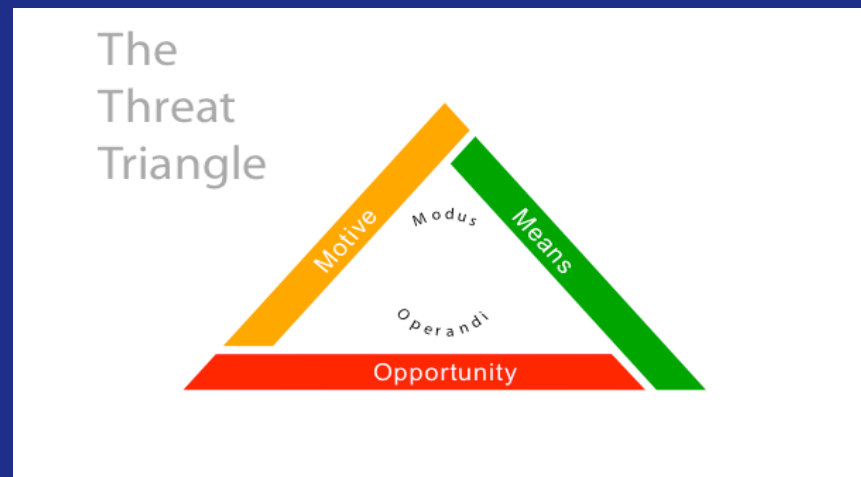
- Evaluate threat potential and consequences of each scenario
- Determine acceptable and unacceptable risks; develop risk statement

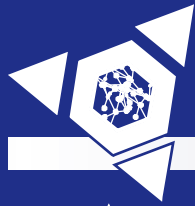




Assessing Threats

- **Motive**
 - **The reason for the crime.** Motivations include ideological, personal, economic, and psychotic. Motivations give rise to a particular intent or objectives. They also impact behavior (e.g., passive or active, violent or nonviolent).
- **Means**
 - **The tools used to commit the crime.** Tools include: knowledge (general and specific); equipment (e.g., tools, weapons, explosives, transportation); and people (willing, coerced or unknowing). For an outsider – an insider can be a tool.
- **Opportunity**
 - **The occasion** that presents itself to allow a crime (e.g., theft or sabotage) to take place.





Biosecurity Risk Assessment: Characterize the Biological Agents

- Assess value of the agents from an adversary's perspective
 - Consequences
 - To the Population
 - Transmissibility
 - Mortality
 - Morbidity
 - Economic
 - Psychological
 - Task Complexity
 - Acquisition
 - Natural
 - Laboratory
 - Synthetic biology
 - Production
 - R&D
 - Covert production
 - Ease of storage
 - Dissemination
 - Route of infection (e.g., aerosol, ingestion)
 - Environmental hardiness

REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org

Journal of Virology, Feb. 2001, p. 1205-1210
0022-538X/01/504-01+0 DOI: 10.1128/JVI.75.3.1205-1210.2001
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Vol. 75, No. 3

Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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Cell Biology, John Curtin School of Medical Research, Australian National University,² Canberra, Australia*

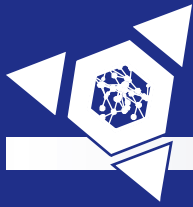




Biosecurity Risk Assessment: Characterize the Adversaries

- **Adversary Classes**
 - Terrorist
 - Extremist
 - Criminal
- **Insiders**
 - Authorized access to the facility, dangerous pathogens, and/or restricted information
 - Distinguish Insiders by level of authorized access
 - Site
 - Building
 - Asset
- **Outsiders**
 - No authorized access





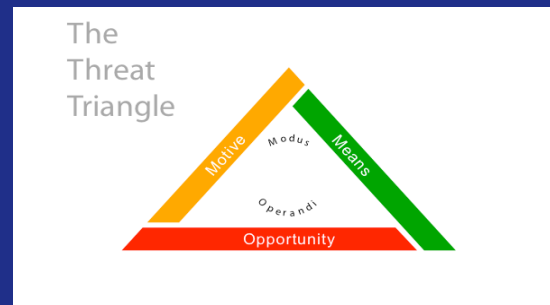
Threats to Bioscience Facilities: Insiders vs. Outsiders

Scenarios involving Insiders generally pose a higher risk than scenarios involving only Outsiders

Insiders

- Access to facility and buildings where biological agents are stored and used
- Can wait for an opportune time
- Have knowledge of facility operations and security system
- Some have relevant technical skills and know how to covertly remove the desired biological agent

- **Opportunity – yes**
- **Means – yes**
- **Motive – ?**



Outsiders

- Most biological agents can be readily found elsewhere: **other laboratories and in nature**
- Do not have authorized access
- Have limited knowledge about facility operations and security
- Will not know exactly where the desired biological agent is stored
- Collusion with an Insider increases risk of detection

- **Opportunity – significantly less**
- **Means – typically less**
- **Motive – ?**



Characterize the Facility

- **Identify “specific adversaries”**
 - Operational Means
 - Opportunity
- **Identify “specific assets”**
 - Uniqueness of asset at facility
 - Location of asset
 - State of asset (e.g. in long-term storage, in active research, type of research, quantity, ...)
- **Facility vulnerabilities**





Traditional Biorisk Assessment Method

- **Typical risk assessment approaches use pure opinion to define the risk**
 - Lacks ability to repeat
 - Can not be compared
 - Difficult to communicate
- **Laboratories often default to regulations to define biorisk practices**



Pure Quantitative Biosecurity Risk Assessment?

- In a quantitative scheme, the risk assessor assigns numerical values to the likelihood and consequences of the adverse event
 - All data in the model should be quantitative
- For laboratory biorisks, currently there is limited data to numerically define the probability of an infection, exposure, release, theft, or loss
- Likewise, there is limited data existing to quantify the consequences of disease



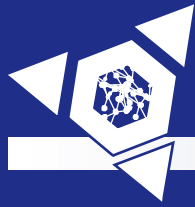
Key things to think about regarding biorisks

- Biorisk and scientific expert opinions are valuable
- The overall biorisk(s) for any process is made up of multiple factors
 - Agent factors like route of infection, impact of disease on a host, etc
 - Laboratory factors like equipment in use, animals in use, in place biosafety practices, etc
 - Environmental factors like susceptible hosts, endemicity, etc
 - Threats for intentional (biosecurity) risks
- Not all factors impact the risk in the same way



One Biorisk Assessment Option

- **Multiple criteria decision making has been widely accepted as a method to capture, compare, and aid in complex decision making processes**
 - Multi-Attribute Utility Theory (MAUT) is one method that has been used for assessment of risks and assessing risk management options
- **Criteria can be organized in terms of likelihood and consequence**
 - And can be arranged in a hierarchy by relationships
- **Criteria can be weighted to reflect the variance of impact**
- **Criteria can be defined using absolute values**



Biosecurity Risk Variables in More Detail

$$\text{Biosecurity Risk} = \left(\text{Threat Potential} \right) * \left(\text{Consequences} \right)$$

Consequences = *Population, Economic, Psychological, Operational*

Threat Potential = *Site Vulnerability, Agent Task Complexity, Adversary Attributes*

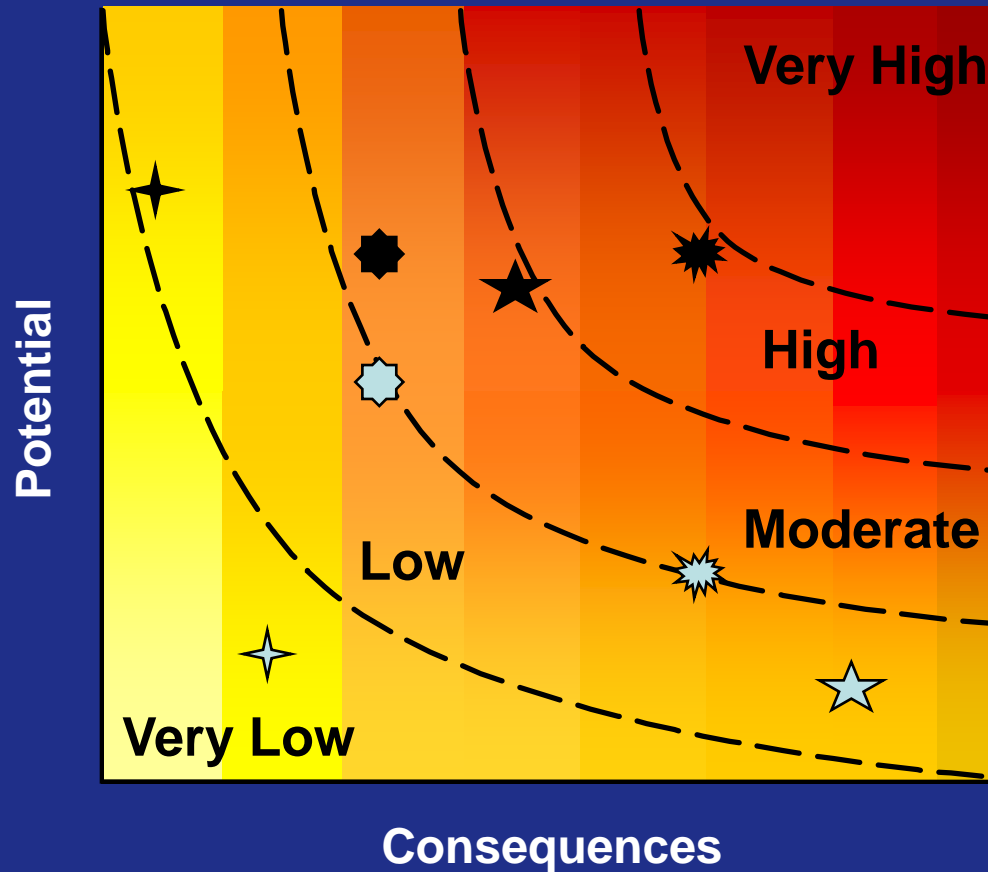
Adversary Attributes = *Motive, Means, Opportunity*

Agent Task Complexity = *Acquisition, Development, Dissemination*

Site Vulnerability = *Physical Security, Personnel Security, MC&A, Information Security, Transport Security, Program Management*

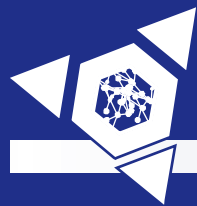
Reference: Laboratory Biosecurity Handbook,
by Reynolds M. Salerno, Jennifer Gaudioso
CRC; 1 edition (June 20, 2007) ISBN-10: 0849364752

Characterizing Scenarios by Risk: Hypothetical Results

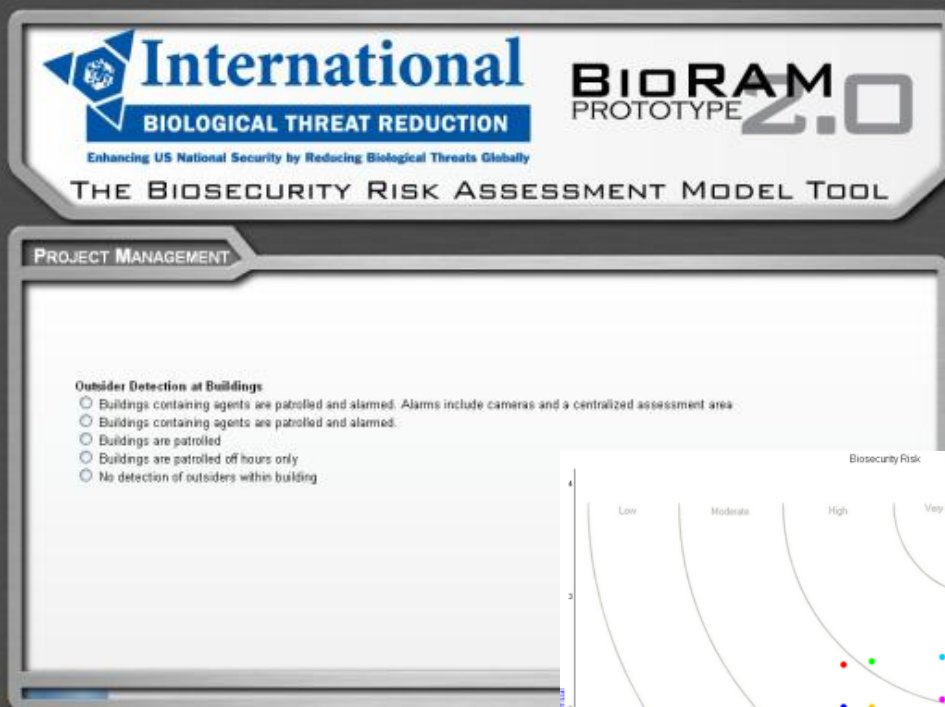


- Protect against unacceptable risk scenarios

- Develop incident response plans for acceptable risk scenarios



Laboratory Biosecurity Risk Assessment Project (Biosecurity RAM)

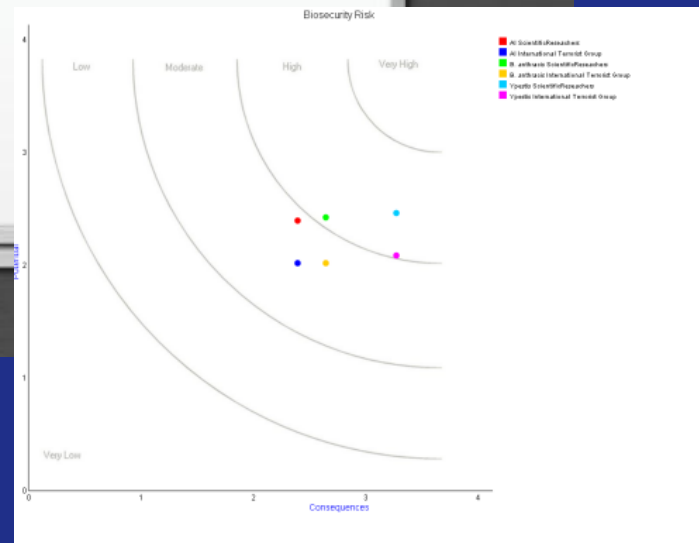


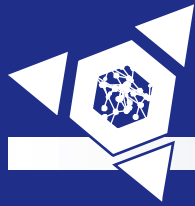
Review Assessment for BAI Post Upgrade

| Agent | Adversary | Consequences | Threat Potential |
|-------------------------|-------------------------------|--------------|------------------|
| Avian Influenza | Scientist/Researchers | 1.61 | 2.77 |
| Avian Influenza | International Terrorist Group | 1.61 | 2.39 |
| B. anthracis | Scientist/Researchers | 2.74 | 2.75 |
| B. anthracis | International Terrorist Group | 2.74 | 2.33 |
| B.S.E. | Scientist/Researchers | 1.49 | 2.66 |
| B.S.E. | International Terrorist Group | 1.49 | 2.23 |
| Brucella | Scientist/Researchers | 1.62 | 2.84 |
| Brucella | International Terrorist Group | 1.62 | 2.41 |
| Classical Swine Fever | Scientist/Researchers | 2.16 | 2.86 |
| Classical Swine Fever | International Terrorist Group | 2.16 | 2.48 |
| E.coli | Scientist/Researchers | 0.73 | 2.73 |
| E.coli | International Terrorist Group | 0.73 | 2.3 |
| HMP | Scientist/Researchers | 2.3 | 3.04 |
| HMP | International Terrorist Group | 2.3 | 2.63 |
| Hemorrhagic septicemia | Scientist/Researchers | 1.89 | 2.81 |
| Hemorrhagic septicemia | International Terrorist Group | 1.89 | 2.38 |
| NewCastle Disease Virus | Scientist/Researchers | 2.84 | 2.76 |
| NewCastle Disease Virus | International Terrorist Group | 2.84 | 2.34 |
| Pasteurella | Scientist/Researchers | 1.1 | 2.73 |
| Pasteurella | International Terrorist Group | 1.1 | 2.31 |
| Rabies | Scientist/Researchers | 2.16 | 2.64 |
| Rabies | International Terrorist Group | 2.16 | 2.21 |
| Salmonella | Scientist/Researchers | 1.34 | 2.78 |
| Salmonella | International Terrorist Group | 1.34 | 2.35 |

[Chart](#)

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Are there other options?

- **There are multiple risk assessment models and methods which can be used to conduct biosecurity risk assessments**
- **The key points for conducting a risk assessment are:**
 - Risk is a function of both the likelihood and the consequences
 - Regulations or risk group definitions are not enough
 - A risk assessment should be repeatable, comparable, and support risk management decision making
- **The approach used should clearly answer the question**
 - E.g. What is the risk of a laboratory acquired infection to someone working on this research project in my lab?
 - E.g. What is the risk of an environmental exposure from this research project?
 - E.g. What is the risk of theft of this valuable biological material from my laboratory?



Biosecurity Risk Assessment

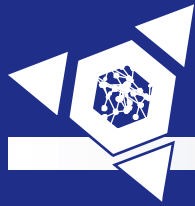
- **Enables the professional (e.g. biosafety officer, responsible official) to:**
 - Become familiar with the proposed work activities (procedures, equipment, personnel)
 - Be a knowledgeable and credible partner with the investigator to develop a safe and secure environment for the work.
 - Support biosecurity risk management decisions
 - Establish appropriate mitigation measures commensurate with the identified biosecurity risks

Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:



- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"



Questions?

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